REMARKS

Summary Of The Office Action

Claims 1-46 are pending in the application.

Claims 1-7, 9-27, 29-32 and 34-45 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Panescu in U.S. Patent Number 6,179,835.

Claims 8, 28, 33, and 46 were objected to as being dependent on a rejected base claim, but allowable if rewritten in independent form.

Claims 1-15, 18, 22, 26, 27, 31, 43 and 44 were rejected under 35 U.S.C. § 102 as being indefinite.

Summary of Applicant's Response

Applicant explains why the variable electrical resistive body of the present invention is not anticipated by the expandable-collapsible electrode assemblies for endovascular treatments described by Panescu et al (6,179,835).

Applicant has amended claims 1-15, 18, 22, 26, 27, 31, 43 and 44 to further clarify the claimed invention.

Applicant has amended dependent claims 8, 28, 33, and 46 to make them allowable by rewriting with the base claims.

Claims 19-20 have been canceled.

New claims 47 and 48 have been added.

Applicant's Detailed Response

Applicant has amended the specification at page 20, line 22 to clarify that the insulator layers (reference number 244) are exactly the same in both the Types "A" and "B" embodiments of FIGS. 10A and 14. At page 4, lines 16-17, the Applicant stated that "like reference numerals are used to identify like elements throughout this disclosure", and for this reason re-statement of the reference numerals was not thought to be necessary. Drawing amendments were made in FIGS. 10A, 10B, 11A and 14 as described above.

In claim 1 and the claims depending therefrom, the Applicant clarified the relation of the engagement plane and the working end by substituting the term "tissue-engaging surface" as the portion of the electrosurgical probe that is at the exterior of the probe for engaging tissue.

In claim 1, and throughout the claim set, the Applicant further clarifies the core aspect of the invention by using the term "variable electrical resistive body" which carries the "tissue-engaging surface". Claim 1 defines one type of variable electrical resistive body by its property of providing low resistance electrical current paths therethrough at a first lower temperature, and wherein the body displays increased resistance electrical current paths at a selected higher temperature. This terminology is used throughout the claims to clarify properties of the temperature-sensitive variable resistive body of the invention.

The core aspect of the invention relates to the variable electrical resistive body carried at a probe's working end. In one exemplary embodiment, the variable electrical resistive body defines a positive temperature coefficient of resistance so that in a low temperature range, current will pass through the variable resistive body about a multiplicity of high conductivity paths. When the engaged tissue is elevated is temperature by ohmic heating, this also elevates the temperature of the variable resistive body by conduction, either locally or globally. At a pre-selected temperature range, the variable resistive body increases in resistance and then will allow current flow therethrough only along increased resistance (low conductivity) paths. At a pre-selected maximum temperature, the variable resistive body can terminate current flow therethrough. Thus, the variable resistive body of the probe working end can self-modulate current flow therethrough in the pre-selected temperature range as the tissue and the variable resistive body change in temperature—wherein the temperature change results from thermal relaxation and convection in the engaged tissue that conducts heat away from the working end.

The clarifications described above explain why the invention is not anticipated by Panescu et al ('835 patent). The Panescu patent discloses a family of expandable-collapsible electrode assemblies for ablating endovascular tissue to treat cardiac arrhythmias. In the '835 patent, the collapsible electrode assembly typically is a balloon structure.

In the Panescu disclosure, there is no mention of any instrument components that have variable electrical resistance in which the component changes its electrical resistance during use to modulate electrical energy applied to the engaged tissue. Claim 1 of the '835 patent explains the Panescu working end as comprising a "family" of collapsible electrode assemblies—with each family member being an "electrically conductive polymer body of a predetermined different

resistivity…." Conductive polymers with a set, predetermined conductivity are a common material.

The Applicants' invention clearly teaches away from the Panescu disclosure. The working end of the present invention carries a variable electrical resistive body in which the resistance is not a set, predetermined number of ohms-cm. The specialized doped polymers used in the present invention are for the first time disclosed for use in electrosurgical probes, wherein the polymer defines a temperature coefficient of resistance. In one embodiment, the present invention provides a working end body that will continually vary in resistance during use—and thereby continually modulate energy application to tissue during such use. Of particular interest, the variable electrical resistive body of the present invention will continuously modulate resistivity in response to either, temperature, pressure or both.

The Applicant describes throughout the specification, for example at p. 27, lines 8-14, that the variable electrical resistive body or "matrix 840B can be a positive temperature coefficient material (PTC) or a negative temperature coefficient material (NTC)…." Each of these types of variable electrical resistive bodies is adapted to control electrical energy density in engaged tissue in a different manner for different therapeutic procedures. The Panescu disclosure does not describe the use of such temperature coefficient polymers. The '835 disclosure only discloses polymers with a predetermined fixed electrical resistance: "The conductivity of the polymer used preferably has a resistivity close to the resistivity of tissue (i.e., about 500 ohm-cm)." Col. 38, lines 12-14.

The Applicant describes the advantages of the present invention, for example at p. 14, lines 20-24:

> "In operation, the working end *automatically* modulates active Rf energy density in the tissue as the temperature of the engaged tissue conducts heat back to the thermally sensitive resistor material 140B to cause its temperature to reach the selected switching range. In this range, the Rf current flow will be reduced, with the result being that the tissue temperature can be maintained in the selected range without the need for thermocouples or any other form of feedback circuitry mechanisms to modulate Rf power from the source."

In contrast, the Panescu disclosure explains that the '835 invention requires other prior art means to control energy delivery:

> "Various methodologies can be used to control the application of radio frequency energy.... The previously described D_{50C} Function can be used, as can the previously described Duty Cycle and Temperature Disabling techniques... [S]uch structures also lend themselves to the use of a proportional integral differential (PID) control technique. Illustrative PID control techniques usable in association with these electrode structures are disclosed in copending U.S. patent application Ser. No. 08/266,023, filed Jun. 27, 1994, entitled "tissue heating and ablation systems and methods using time-variable set point temperature curves for monitoring and control." Col.38, lines 24-41.

Thus, the Applicant's inventive apparatus and method for controlling Rf energy delivery to tissue is not anticipated by Panescu.

In Claim 9, the term "resilient" was substituted for "flexible" to clarify the invention. Temperature coefficient polymers are entirely different from common conductive polymers, for example as described in the Panescu disclosure. A conductive polymer as used by Panescu can be any plastic with some conductive material mixed therein. In contrast, the temperature or pressure coefficient polymers of the present invention are matrices of particular non-conductive polymers and conductive particles that display extraordinary changes in electrical resistance under a specified temperature or pressure change. Most often such temperature or pressure coefficient polymers have mis-matches in physical properties of the two components (non-conductive polymer and conductive particles) so that temperature or pressure alters the current paths in the body that are defined by the multiplicity of conductive particles.

Claim 16 was amended to explain that the "delivering Rf energy" step causes ohmic heating in the tissue (Rf energy density) which is then modulated by the variable resistive body. This makes clear that Claim 18 further limits claim 16, wherein claim 18 applies energy to the tissue by "means of <u>conduction of heat</u> through the tissue-engaging surface from said variable electrical resistive body." This comprises an inventive part of the method, wherein the working end applies energy for the first time in two cooperating .manners: (i) initially by applying Rf energy to cause "active" ohmic heating, and (ii) thereafter by applying heat by "passive" conduction from the thermal capacity of the working end. By modulating energy application between active ohmic heating and passive conductive heating, it has been found that a targeted temperature can be controlled and maintained to cause very uniform tissue heating.

Claim 16 also was amended to clarify that this claim related only to a method of using a "temperature-sensitive" variable electrical resistive body. In its original version, claim 16 broadly claimed the invention of applying energy with a variable electrical resistive body—wherein dependent claim 17 claimed the use of "temperature-sensitive" variable electrical

resistive materials and claim 20 claimed the use of "pressure-sensitive" variable electrical resistive materials. Claim 20 is canceled. Hence, to clarify matters, independent claim 16 and its dependent claims now relate only to "temperature-sensitive" variable electrical resistive bodies. New claim 47 was added as a method claim using a probe with a "pressure-sensitive" variable electrical resistive body. New Claim 48 was added as an apparatus claim for an Rf probe with a conductor having a surface layer of a pressure variable resistor ink.

Claims 21 and 22 were amended to clarify the number and location of the electrodes of the working end. Claim 21 now described an interior electrode with a first polarity at an interior of the body. Claim 22 described a surface electrode of an opposing polarity within the exterior surface of the body. An additional error is corrected, by canceling one or two claims originally numbered as claim 22.

Conclusion

Applicant respectfully submits that in view of the foregoing amendments and remarks, the present application is in condition for allowance. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (650) 938-0196.

Respectfully submitted,

Csaba Truckai